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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985

23535 7590 12/28/2004
MEDLEN & CARROLL, LLP
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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,059

Applicant(s)

BAKER ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-74, 76-86, 90-95, 97, 98, 101-108, 110, 111, 115-117, 120-123, 125, 127, 128 and 130 is/are rejected.
- 7) ☒ Claim(s) 75, 87-89, 96, 99, 100, 109, 112-114, 118, 119, 124, 126 and 129 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of Terminal Disclaimer, amendment and remarks, all filed 09/21/04. Claims 1-70 are cancelled by the amendment and new claims 71-130 are added.

Claim Rejections - 35 USC § 112

1. The rejection of claims 15, 16, 18, 19, 28, 29 and 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because of the cancellation of claims 15, 16, 18, 19, 28, 29 and 44. Applicants' argument regarding polysorbate is persuasive and thus new claims 92 and 103 reciting polysorbate are not rejected.

Claim Objections

2. Claims 116-119 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 116-119 fail to further limit the method of modifying the emulsion.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 1, 2, 4, 6-10, 14-18, 20, 23, 25, 26, 28-31, 33, 35-38, 40, 42, 44, 46-53, 55-57, 61-63, 65 and 67-70 under 35 U.S.C. 102(e) as being anticipated by Baker, Jr. et al. (US 6,015,832) is withdrawn because claims 1-70 are cancelled by the amendment filed 09/14/04. The new claims now recite compositions that contain halogen-containing compound. Applicants' specification in paragraph [0111] lines 5-8 of the published application state that "suitable halogen containing compounds may be selected, for example, from compounds comprising chloride, fluoride, bromide and iodide ions" and paragraph [0023] of the published application state that in some preferred embodiments "the halogen-containing compound comprises a cetylpyridinium halides, cetyltrimethylammonium halides, cetyldimethylethylammonium halides, cetyldimethylbenzylammonium halides, cetyltributylphosphonium halides, dodecyltrimethylammonium halides, tetradecyltrimethylammonium halides, cetylpyridinium chloride, cetyltrimethylammonium chloride, cetylbenzyltrimethylammonium chloride, cetylpyridinium bromide, cetyltrimethylammonium bromide, cetyldimethylethylammonium bromide, cetyltributylphosphonium bromide, dodecyltrimethylammonium bromide, or tetradecyltrimethylammonium bromide." While Baker (US 6,015, 832) discloses in column 1, lines 58-60 and column 7, lines 65-67 that sodium hypochlorite, a halogen containing compound, inactivates bacterial spores, a combination of the emulsion of Baker that does not contain halogen containing compound and hypochlorite composition, which inactivates bacterial spore, would not render the new claims obvious under 35 USC 103(a) based on In re Kerkhoven since

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halogen containing compounds are described by applicants to be other than hypochlorite. Thus, applicants' argument as it relates to new claims 71 is persuasive because Baker's composition does not contain halogen-containing compound and would not even under *In re Kerkhoven* contain halogen-containing compound of the type applicants refer to as halogen containing compound.

6. The rejection of claims 1, 3-6, 8-10, 15-23, 27-30, 32-36, 39, 40, 43-53, 60-63, 65, 67 and 68 under 35 U.S.C. 102(e) as being anticipated by Schwarz (US 6,117,4115) is withdrawn because of the cancellation of claims 1-70 and also, and because of the date of the reference as pointed out by applicants. Schwarz is not applied against the new claims.

The following rejections are however made under 35 USC 102.

7. Claims 71-74, 76-78, 80-86, 90-95, 97, 98, 101-108, 110, 115, 120-123, 125, 127, 128 and 130 are rejected under 35 U.S.C. 102(b) as being anticipated by Spitzer et al. (US 3,912,666).

Spitzer discloses oil-in-water emulsion (abstract, column 6, line 34) that contains halogen compound such as vinyl chloride, methyl chloride, propellants and Freon and halogenated solvents (column 6, line 66 to column 7 line 9; column 8, lines 57-64), oil phase and aqueous phase (column 9, lines 31-42), surfactant such as sodium dodecyl sulfate, polyethylene glycol esters, cetyltrimethylammonium bromide (column 10, lines 16-67), ethyl alcohol or methyl alcohol or isopropyl alcohol or glycerol (column 11, lines 15-19). Cetyltrimethylammonium bromide is also a halogen-containing compound, of the type applicants regard as halogen-containing compound, that has deodorizing and antiseptic properties (column 12, lines 18 and 19). Spitzer discloses that the oil-in-water emulsion composition is topically applied as

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cleansing, conditioning, coating, lubricating agents, personal washing, laundering, dishwashing, shampoos, shaving cream, hair color and rinses (column 12, line 58 to column 13 line 13); Spitzer's oil-in-water emulsion composition is also useful as furniture and shoe cleaners and polish (column 13, lines 14-20). Spitzer's oil-in-water emulsion composition may also contain medicaments such as antimicrobial agents (column 13, lines 22-61). Regarding medical device, applicants' specification in paragraph [0091] of the published application defines medical device as a "drug delivery devices" and Spitzer incorporates medicaments such as histamines, sulfa drugs, antibiotics, hormones, vitamins, antimicrobials agents and procaine (column 13, lines 22-53). See also Examples 1-2. The aqueous phase in Spitzer is about 10% to about 75% by weight of the emulsion and by corollary (claim 17), the oil phase would be from about 90% to about 25% by weight of the emulsion and since the density of the emulsion would not be drastically different than the density of water at 1, the weight percent would approximate volume percent. Spitzer meets the limitations of the claims.

8. Claims 71-74, 78-86, 92-95, 97, 98, 102-108, 110, 111, 115-117, 120-123 and 127 are rejected under 35 U.S.C. 102(e) as being anticipated by Little-van den Hurk et al. (US 5,951,988).

Little-van den Hurk discloses oil-in-water emulsion that contains halogen containing compound (column 2, lines 12-56), oil selected from the group consisting of mineral oils, vegetable oils and animal oils (column 2, lines 58 and 59; column 4, lines 29-54), ethanol (column 4, line 60), sodium lauryl sulfate (column 5, lines 2-14), phosphate buffered saline (column 5, line 19), and the emulsion may contain TWEEN (example 1). The vegetable oils include canola oil, almond oil, cottonseed oil, corn oil, olive oil, peanut oil, safflower oil and

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sesame oil (column 4, lines 52-54). The oil-in-water emulsion composition is administered to animals and a measure of the immune response is assayed (Example 2). The formulation of Little-van den Hurk contains lower alcohols such as ethanol, isopropanol and butanol (column 4, lines 59 and 60). The teachings of Little-van den Hurk meet the limitations of the claims.

Claim Rejections - 35 USC § 103

9. The rejection of claims 11-13, 37, 58, 59 and 66 under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,015,832) is not sustained because of cancellation of claims 1-70 and also in light of the discussion on Baker above.

New claims 118 and 119 are directed to method of doing business in an effort to sell a product and these claims appear not to belong with the rest of the claims. The advertisement issue may raise questions of statutory concerns because advertisements may be non-statutory matter and the patentable utility of advertising and selling appear to be lacking. It is respectfully submitted that any pharmaceutical product invention has the ultimate goal of reaching a consumer market that is inherent in the method of doing business or that is an unspoken understood goal of the invention. Applicants did not respond to this issue raised in the last office action

10. The rejection of claims 24, 41, 54 and 64 under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US 6,117,415) is not sustained because claims 1-70 are cancelled and in light of the date of Schwartz.

Double Patenting

Receipt is acknowledged the Terminal Disclaimer filed 09/21/04 and the rejection is withdrawn.

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11. Claims 75, 87-89, 96, 99, 100, 109, 112-114, 124, 126 and 129 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
 12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barchfeld discloses oil-in-water emulsion (abstract, column 3, line 62; column 8, lines 6-9) comprising vegetable oil (peanut oil, soybean oil, coconut oil, olive oil, safflower oil, cottonseed oil, sunflower seed oil, sesame seed oil, sunflower seed oil, corn oil) or fish oil (squalene) or animal oil or synthetic oil (column 11, lines 45-53; column 12, lines 15-22; column 12, lines 53-55), surfactants such as polysorbate, TWEEN, benzalkonium chloride, cetylpyridinium chloride (column 13, line 45 to column 16, line 46). The composition of Barchfeld does not contain alcohol.
 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
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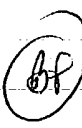
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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